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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,516	12/05/2003	Tracee Eidenschink	S63.2B-11293-US01	9041
490	7590	12/13/2006	EXAMINER	
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			KOTINI, PAVITRA	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,516

Applicant(s)

EIDENSCHINK ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 and 39-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/30/05, 3/11/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 15-34 and 39-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/06.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Precisely, the description of the invention is unclear as to how the stent structure is restricted from expanding to a full diameter due to the disengagable connector struts. The specification states that the stent with disengagable connector struts allows for partial or intermediate expansion of the stent. Full diameter is achieved once the disengagable connector struts are electrically eroded. However, it is not enabling how the permanent connector struts *do not* limit the stent diameter, but the disengagable connector struts *do* limit the expansion of the self-expanding struts.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 13, 14, 35, 36, 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al (US 2004/0002752).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Griffin discloses:

Regarding **claim 1**, a plurality of serpentine bands (fig.2, 108); adjacent serpentine bands being connected to one another by at least one permanent connector strut (fig.2, 114); adjacent serpentine bands being connected to one another by at least one disengagable connector strut which may be disengaged by electrolytic detachment (para.0047).

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Regarding **claim 2**, said at least one disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said serpentine bands (0049).

Regarding **claim 7**, the stent is at least partially self-expanding (para.0044).

Regarding **claim 13**, upon disengagement of said at least one disengagable connector strut, said at least one disengagable connector strut no longer transmits forces between said adjacent serpentine bands. (inherent)

Regarding **claim 14**, said serpentine bands (fig.2, 108) further comprise a plurality of alternating peaks and valleys (fig.2, 110 and 112); wherein said at least one permanent connector strut connects at a first end to a valley of one serpentine band and connects at a second end to a peak of an adjacent serpentine band (fig.2); and wherein said at least one disengagable connector strut connects at a first end to a valley of one serpentine band and connects at a second end to a peak of an adjacent serpentine band (para. 0047).

Regarding **claim 35**, a cylindrical metal framework (para.0044) having a plurality of cells (fig.2), said framework comprising a first serpentine band, a second serpentine band, a permanent connector strut (fig.2, 114) connecting the first serpentine to the second serpentine band (fig.2), and a disengagable connector strut connecting the first serpentine to the second serpentine band (fig.2, 120); wherein the number of cells decreases upon disengagement of said disengagable connector strut (inherent); and wherein the mass of the metal framework decreases upon disengagement of said disengagable connector strut (inherent).

Regarding **claim 38**, the stent is at least partially self-expanding (para.0044).

Regarding **claim 36**, cells on either side of said disengagable connector strut combine to form a single cell upon disengagement of said disengagable connector strut (it is inherent that when the disengagable connector strut is eroded, the adjacent cells would combine into one).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al (US 2004/0002752) in view of Frantzen (US 5873907).

Griffin discloses the invention substantially as claimed above.

Regarding **claim 3**, Griffin does not disclose an electrical lead. However, Frantzen teaches an electrical lead (fig.3A, 32) that is electrically coupled to the stent (fig.3A, 10). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent disclosed by Griffin to include an electrical lead coupled to the stent, as taught by Frantzen. Such a modification would provide the direct electrical energy necessary to erode the disengagable connector struts.

Regarding **claims 4 and 5**, Griffin discloses a plurality of disengagable connector struts, but Griffin does not disclose an electrical lead to be electrically coupled to at least one or plurality of disengagable connector strut. However, Frantzen teaches coupling of the electrical lead (fig.3A, 32) to disengagable connector struts (fig.3A, 30) on stent (fig.3A, 10). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent with disengagable connector struts disclosed by Griffin to include an electrical lead coupled to the disengagable connector struts as taught by Frantzen. Such a modification would provide the apparent advantage of ensuring corrosion of the disengagable struts by a direct electrical lead.

Regarding **claim 6**, Griffin discloses a plurality of disengagable connector struts, but does not disclose a second electrical lead, wherein each electrical lead connects to at least one disengagable connector strut. However, Frantzen teaches two electrical leads; one is (fig.3B, 32a) and the second is (fig.3B, 32b), wherein each electrical lead connects to at least one disengagable connector strut (fig.3B, 30). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent with disengagable connector struts disclosed by Griffin to include a second electrical lead connected to the disengagable connector strut as taught by Frantzen. Such a modification could provide the advantage of having each electrical lead contact the disengagable strut at a different location (col.3, lines 55-60).

Regarding **claim 8**, as best understood, Griffin does not disclose the stent to self-expand to an intermediate deployment diameter, the stent being restrained from further expansion by said at least one disengagable connector strut. However, Frantzen

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teaches a stent that self-expands partially (col.2, lines 16-19), wherein the stent (fig.3A, 10) is restrained by at least one disengagable connector strut (fig.3A, 30; col.2, lines 4-6).

Regarding **claim 9**, the stent self-expands to a full deployment diameter upon disengagement of said at least one disengagable connector strut (it is inherent that the self-expanding stent with connector struts as taught by Frantzen will eventually reach full diameter once the last disengagable connector strut is disengaged).

Regarding **claim 10 and 11**, Griffin discloses at least one disengagable connector strut, but fails to disclose a necked portion on the disengagable connector strut and that the disengagement occurs at the necked portion. However, Frantzen teaches a necked portion (fig.3B, 36a), which is the site of electrical corrosion. Such a modification would provide the apparent advantage of the faster disengagement due to the reduced diameter or thickness.

Claim 12 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al (US 2004/0002752).

Griffin discloses the invention substantially as claimed above.

Regarding **claim 12**, Griffin does not specifically state that the disengagable connector strut is connected to a serpentine band at a necked portion. However, Griffin does teach that the disengagable connector struts may be placed anywhere along the stent (para.0047). The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the detachable segment stent. Applicant has not disclosed that the disengagable connector strut

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connected to a serpentine band at a necked portion provides an advantage, is used for a particular purpose or solves a stated problem. As such this parameter is lacking in any criticality and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Regarding **claim 37**, Griffin does not disclose specifically, the location of each permanent or disengagable connector struts. However, Griffin does disclose that the disengagable connector struts may be placed at any desired location (para.0047). Therefore, it is simply a matter of preference as to where the disengagable struts would be placed. Furthermore, the Applicant has not provided any criticality to the any specific arrangement of the disengagable and permanent struts. Lastly, it is inherent and obvious that once all the disengagable connector struts are all disengaged, the only struts separating the cells will be the permanent strut. Hence, it is inherent that a portion of each cell will be defined by a portion of a permanent connector strut after disengagement of said disengagable connector strut.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pavitra Kotini
AU 3731



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/5/06